Medtrade

Innovative Medical Products

K093593
Page 1/3

SECTION 2: **510(k) SUMMARY**

2.1 Sponsor

MedTrade Products Limited
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Registration Number: 9614493

Contact Person: Jonathan Ranfield
Director, Quality Assurance & Regulatory Affairs

2.2 Date Summary was Prepared

November 11, 2009.

2.3 Device Information

Proprietary Name: CELOX PRO for Minor External Bleeding from Wounds and Procedures

CELOX PRO for Moderate to Severe External Bleeding Wounds

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Common Name: Hemostatic Granules Wound Dressing

Classification Name: Dressing, Unclassified

5.4 Predicate Device

MedTrade Products Limited: CELOX Topical Hemostatic Granules (K061079)

Biolife, L.L.C; PRO QR (Quick Relief) Powder (K080210)

Medafor, Inc.; HemaDerm (K021678)

5.5 Device Description

Components – CELOX PRO is composed of chitosan, polymer, poly-N-acetylglucosamine.

Mechanism of Action – CELOX Pro achieves its principle intended action (hemostasis) by creating a physical barrier or seal to stop the flow of blood. When poured on a wound and upon contact with blood or exudate, in combination with manual pressure to the wound, CELOX PRO quickly forms a strong seal that completely covers the wound.

5.6 Intended Use

CELOX PRO for minor external bleeding from wounds and procedures (Rx) is intended for use as a temporary topical dressing for bleeding control associated with minor wounds, including control of minor external bleeding and exudate from sutures and/or surgical procedures.

CELOX PRO for moderate to severe external bleeding wounds (Rx) is intended for temporary external treatment for controlling moderate to severe bleeding.

CELOX PRO for minor external bleeding from wounds and procedures is intended for OTC use as a temporary topical dressing for bleeding control associated with minor wounds, including control of minor external bleeding and exudate from sutures and/or surgical procedures.

5.7 Substantial Equivalence

CELOX PRO has substantially equivalent indications to the PRO QR (K080210) and HemaDerm (K021678) predicates in that they are indicated for topical application as an aid in the control of temporary external bleeding associated with minor to severely bleeding wounds. CELOX PRO uses the same safe and effective technology as CELOX Topical Hemostatic Granules (K061079). The subject device and predicate devices are made from materials which have demonstrated satisfactory biocompatibility, are highly absorbent for collecting body fluids, and are sterile, single use devices.

5.8 Performance Testing

Biocompatibility Testing-

Identical to CELOX Hemostatic Granules, previously provided and reviewed and cleared under (K061071).

In vitro Testing

To support: No Heat Generated in Use, Promoting Rapid Coagulation & Hepranized Blood and Works in Hypothermic Conditions, identical to CELOX Hemostatic Granules, previously provided and cleared under (K061071).

To support: Promoting Rapid Coagulation & Warfarin / Coumadin Blood identical to CELOX topical Hemostatic Granules in Soluble Bag, previously provided and cleared under K072328

Animal Studies

Animal Study 1 – Preliminary study of CELOX severe topical arterial bleeding model Protocol & Report to establish method.

Animal Study 2 – CELOX PRO Severe topical arterial bleeding model Protocol & Report full study.

Clinical Study – Not Applicable.

5.9 Conclusion

CELOX PRO induces hemostasis by the absorption of water in the blood to form a robust gel plug the same as CELOX Topical Hemostatic Granules (K061079) predicate device.

CELOX Hemostatic Granules (have been shown in testing to be equivalent to, if not better than, the QuikClot Powder predicate device in rapid haemorrhage control in a swine model of lethal arterial extremity. (Portsmouth Paper)

Safety and efficacy was also demonstrated for bleeding control in minor external bleeding from surgical procedures using a swine model.

CELOX Hemostatic Granules OTC have been shown in testing to repeatedly control minor external bleeding from surgical procedures swine model.

CELOX Hemostatic Granules have been shown in testing to repeatedly control external bleeding when the animal model has been heparinised.

MedTrade Products believes that, as a result of the biocompatibility testing in vitro testing, and non-clinical animal testing, CELOX PRO is safe and effective as an aid in the control of temporary external bleeding associated with moderate to severe bleeding. CELOX PRO is substantially equivalent to the predicate devices, CELOX, PRO QR and HemaDerm.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

JAN 20 2010

MedTrade Products Limited
% Mr. Jonathan Ranfield
Director, QA/RA
Electra House, Crewe Business Park
Crew, Cheshire CW1 6GL
United Kingdom

Re: K093593
Trade/Device Name: CELOX Pro
Regulatory Class: Unclassified
Product Code: FRO
Dated: November 11, 2009
Received: November 19, 2009

Dear Mr. Ranfield:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093593

Device Name: CELOX PRO

CELOX PRO for minor external bleeding from wounds and procedures (Rx) is indicated for use as a temporary topical dressing for bleeding control associated with minor wounds, including control of minor external bleeding and exudate from sutures and/or surgical procedures.

CELOX PRO for moderate to severe external bleeding wounds (Rx) is indicated for temporary external treatment for controlling moderate to severe bleeding.

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093593

Indications for Use

510(k) Number (if known): K093593

Device Name: CELOX PRO

CELOX PRO for minor external bleeding from wounds and procedures (OTC) is indicated for use as a temporary topical dressing for bleeding control associated with minor wounds, including control of minor external bleeding and exudate from sutures and/or surgical procedures.

Prescription Use _____ AND/OR Over-The-Counter Use ___X____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause

(Division Sign-Off)
Division of Surgical, Orthopedic,
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